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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,261

01/17/2006

Minoru Moriya

BY0006P

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

02/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/544,261	MORIYA ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-53 is/are pending in the application.
- 4a) Of the above claim(s) 46-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-45, 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 33-45, 53 in the reply filed on Nov. 11, 2008 is acknowledged.

Claims 33-45, 53 with example 48 as the elected species are prosecuted. Claims 46-52 are withdrawn from consideration per 37 CFR 1.142(b).

2. This application is a 371 of PCT/JP2004/001326 filed Feb. 9, 2004. The claim to the benefit of priority date of JP 2003-032123 (2/10/2003) is denied because certified copy and certified translation of the foreign priority document was not made of record.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Please note that the definition of the Markush elements are very confusing and the definition contradicts the structural formula at times. Examples are given below but is not an exhausted listing;

Cy is defined as a 5- or 6-membered aromatic carbocyclic group. Please note that 5 membered carbocyclic rings are not aromatic.

Y1-Y4 can be N or methylene. Please note that Y1-Y4 are elements in an aromatic ring, when Y1-Y4 are all methylene which is CH₂, it is not an aromatic ring.

The scope of the claim is very confusing as to what is the meets and bounds of the claim and what is the optional elements of the Markush groups.

4. Claims 33-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Ar or CY and Y1-Y4 combination being selected from the limited scope as found in Tables 1-7 of specification, does not reasonably provide enablement for the claimed scope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The claimed scope encompassed by the claims being:

Ar is a mono- or bi-cyclic aromatic carbocyclic or aromatic heterocyclic group which may have one, two or more substituent groups selected from Group β ;

CY is a cyclic group optionally having one, two or more substituent groups selected from Group α , which cyclic group is selected from: (1) a 3 to 10-membered aliphatic carbocyclic group, (2) a 3 to 10-membered aliphatic heterocyclic group, (3) a 5 or 6-membered aromatic carbocyclic group, and (4) a 5 or 6-membered aromatic heterocyclic group;

Y1-Y4 are independently selected from (1) methylene, which optionally has a substituent group selected from Group α , and (2) a nitrogen atom, with the proviso that not all of Y1-Y4 are simultaneously nitrogen atoms; are drawn to enormous compounds with very confusing structure (see section 3 *supra*).

Compare to the compounds made in the specification especially those variations of Markush compounds that exhibits biological activity (table 1) i.e. Cy is limited to 2-oxopyrrolidinyl, 1-pyrazolyl, 1-imidazolyl, 1-triazolyl, 1-tetrazolyl, or pyridyl with the claimed scope, it is insufficient support that all the compounds encompassed by the claim share substantial structural commonality which is responsible for the claimed utility. Especially, compounds anticipates the generic scope is known and used by "others" which was neither made or founds antecedent basis in the specification (see RN 1026906-40-0).

The starting material, how to make and how to use compounds encompassed by the breadth of the claim are lacking but required. Absent of starting material the specification offered mere language rather than enablement.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 33-44, 53 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Marzabadi et al. WO 2004/004714 (effective filing date 7/3/2002).

See compounds of pages 101-109, table 1 and claims 1-28, process p.45, scheme E and specific process of making examples of pages 101-109.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-45, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marzabadi et al. WO 2004/004714.

The anticipatory compounds in Marzabadi et al. WO 2004/004714 of the generic claims have been clearly identified supra in section 5. The species of claim 45, wherein the spiroisofuranpiperidines differ from the prior art compounds only in the substituents on the phenyl rings. Generically, independent and multiple substitution were described and claimed in the references (see '714, claim 1, p.128). In absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 33-45, 53 rejected under 35 U.S.C. 102(g) as being anticipated by US 2006/0173027.

See claims 1-28, and the instant claims being drawn to spiroisofuranpiperidines.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Feb. 25, 2009

/Celia Chang/
Primary Examiner
Art Unit 1625